



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, DC 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

Data Matrix

Date: October 3, 2017	EPA Reg. No./File Symbol: 71185-4	Page 1 of 7
Applicant's/Registrant's Name and Address: Geo Logic Corporation P.O. Box 3091 Tequesta, FL 33469	Product Name: EAC Streptomycin Manufacturing Use Product	

Ingredients:

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
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158.310: Product Chemistry Data Requirements

830.1550	Product Identity and Composition	44863901	Geo Logic Corp.	OWN	
830.1600	Description of Materials used to Produce the Product	44863901	Geo Logic Corp.	OWN	
830.1620	Description of Production Process	44863901	Geo Logic Corp.	OWN	
830.1670	Discussion of Formation of Impurities	44863901	Geo Logic Corp.	OWN	
830.1700	Preliminary Analysis	44863902	Geo Logic Corp.	OWN	
830.1750	Certified Limits	44863902	Geo Logic Corp.	OWN	
830.1800	Enforcement Analytical Method	44863902	Geo Logic Corp.	OWN	

Physical and Chemical Properties

830.6302	Color	44863903	Geo Logic Corp.	OWN	
830.6303	Physical State	44863903	Geo Logic Corp.	OWN	
830.6304	Odor	44863903	Geo Logic Corp.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	44863903	Geo Logic Corp.	OWN	
830.6317	Storage Stability	44863903	Geo Logic Corp.	OWN	
830.6320	Corrosion Characteristics	44863903	Geo Logic Corp.	OWN	
830.7000	pH	44863903	Geo Logic Corp.	OWN	
830.7050	UV/Visible Absorption	47796501	Geo Logic Corp.	OWN	
830.7220	Boiling Point/Boiling Range				Not required (see endnote 1)
830.7300	Density/Relative Density/Bulk density	44863903	Geo Logic Corp.	OWN	
830.7370	Dissociation Constant in Water	44863903	Geo Logic Corp.	OWN	
830.7550	Partition Coefficient (n-octanol/water)	44863903	Geo Logic Corp.	OWN	
830.7840	Water Solubility	44863903	Geo Logic Corp.	OWN	
830.7950	Vapor Pressure	44863903	Geo Logic Corp.	OWN	

158.400: Product Performance Data Requirements

Signature:

Name and Title:

James Messina
Authorized Representative for Geo Logic Corp.

Date:

10/03/2017



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Applicant's/Registrant's Name and Address: Geo Logic Corporation P.O. Box 3091 Tequesta, FL 33469	Product Name: EAC Streptomycin Manufacturing Use Product	

Ingredients:

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
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158.500: Toxicology Data Requirements

870.1100	Acute Oral Toxicity				Waived (see endnote 2)
870.1200	Acute Dermal Toxicity				Waived (see endnote 2)
870.1300	Acute Inhalation Toxicity				Waived (see endnote 2)
870.2400	Acute Eye Irritation				Waived (see endnote 2)
870.2500	Acute Dermal Irritation				Waived (see endnote 2)
870.2600	Skin Sensitization				Waived (see endnote 2)
870.3100	90-Day Oral Toxicity in Rodents				Waived (see endnote 2)
870.3150	90-Day Oral Toxicity in Nonrodents				Waived (see endnote 2)
870.3200	21/28-Day Dermal Toxicity				Waived (see endnote 2)
870.3465	90-Day Inhalation Toxicity				Waived (see endnote 2)
870.3700	Prenatal Developmental Toxicity Study				Waived (see endnote 2)
870.3800	Reproduction and fertility effects				Waived (see endnote 2)
870.4100	Chronic Toxicity				Waived (see endnote 2)
870.4200	Carcinogenicity – mouse				Waived (see endnote 2)

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Ingredients:

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
870.4200	Carcinogenicity – rat				Waived (see endnote 2)
870.5100	Bacterial Reverse Mutation Test				Waived (see endnote 2)
870.5300	<i>In Vitro</i> Mammalian Cell Gene Mutation Test				Waived (see endnote 2)
870.5375	<i>In Vitro</i> Mammalian Chromosome Aberration Test				Waived (see endnote 2)
870.5385	Mammalian Bone Marrow Chromosomal Aberration Test				Waived (see endnote 2)
870.5395	Mammalian Erythrocyte Micronucleus Test				Waived (see endnote 2)
870.6100	Acute Delayed Neurotoxicity – hen				Waived (see endnote 2)
870.6200	90-Day Neurotoxicity – rat				Waived (see endnote 2)
870.6300	Developmental Neurotoxicity				Waived (see endnote 2)
870.7485	Metabolism and Pharmacokinetics				Waived (see endnote 2)
870.7600	Dermal Penetration				Waived (see endnote 2)
870.7800	Immunotoxicity	49000801	Geo Logic Corp.	OWN	Waiver submitted (see endnote 3)
158.1410: Residue chemistry data requirements					
860.1100	Chemical Identity	46559901	Geo Logic Corp.	OWN	
860.1200	Directions for Use		Geo Logic Corp.	OWN	See Label
860.1300	Nature of the Residue in Plants				Waived (see endnote 4)

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Ingredients:

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
860.1340	Residue Analytical Method - Apples	00103383, 00103386, 00103390, 00108026	Pfizer, Inc. Zoetis, Inc. Zoetis, Inc. Zoetis, Inc.	OLD	
830.1670	Residue Analytical Method - Pears	00103388, 00103377	Zoetis, Inc. Zoetis, Inc.	OLD	
830.1700	Residue Analytical Enforcement Method –apples, Residue Analytical Enforcement Method & ILV -citrus	49537601, TBD	Geo Logic Corp.	OWN	
860.1500	Magnitude of the Residue – Crop Field Trials – Pome Fruits (Apples and Pears)	00103377, 00103386, 00103390	Zoetis, Inc. Zoetis, Inc. Zoetis, Inc.	OLD	
860.1500	Magnitude of the Residue – Crop Field Trials – Grapefruit (RAC & Processed Fractions)	49229401	Interregional Research Project No.4 (IR-4)	PUB	
860.1500	Magnitude of the Residue – Crop Field Trials – Field & Greenhouse Tomatoes (RAC & Processed Fractions)	49229402	Interregional Research Project No.4 (IR-4)	PUB	
860.1500	Magnitude of the Residue – Crop Field Trials – Citrus (RAC & Processed Fractions)	TBD	Geo Logic Corp.	OWN	
860.1850	Confined Crop Rotation Study				Waived (see endnote 5)
860.1550 & 860.1560	Proposed Tolerance and Reasonable Grounds in Support of Petition apples & citrus	49213201, TBD	Geo Logic Corp.	OWN	
158.630: Ecological Effects: Terrestrial and aquatic nontarget organisms data requirements					
850.1010	Invertebrate Toxicity, <i>Daphnia magna</i>	43192201	Pfizer, Inc.	OLD	
850.1075	Freshwater Fish Toxicity, Rainbow trout	00103394	U.S. EPA	OLD	
850.1075	Freshwater Fish Toxicity, Bluegill	00103395	U.S. EPA	OLD	
850.1300	Aquatic Invertebrate Life Cycle - Freshwater	47809001	Nufarm Americas, Inc.	PAY	See endnote 6
850.1400	Fish Early-Life Stage - Freshwater	48893101	Nufarm Americas, Inc.	PAY	See endnote 6
850.2100	Acute Avian Oral Toxicity – Quail	41777701	Zoetis, Inc.	OLD	
850.2100	Acute Avian Oral Toxicity – Mallard duck	41777701	Zoetis, Inc.	OLD	

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Ingredients:

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
850.2200	Acute Avian Dietary Toxicity – Quail	41777702	Zoetis, Inc.	OLD	
850.2200	Acute Avian Dietary Toxicity – Mallard duck	00107412	Merck & Co.	OLD	
850.2300	Avian Reproduction – Mallard Duck	48998301	Nufarm Americas, Inc.	PAY	See endnote 6
850.2300	Avian Reproduction – Quail	48998302	Nufarm Americas, Inc.	PAY	See endnote 6
850.3020	Honeybee Acute Contact Toxicity Test	41777703	Zoetis, Inc.	OLD	
850.4100	Terrestrial Plant Toxicity, Tier 1, Seedling Emergence	48783001	Nufarm Americas, Inc.	PAY	See endnote 6
850.4150	Terrestrial Plant Toxicity, Tier 1, Vegetative Vigor	48782901	Nufarm Americas, Inc.	PAY	See endnote 6
850.2100	Streptomycin Sulfate: An Acute Oral Toxicity Study With The Canary	50404001	Geo Logic Corp.	OWN	
158.660: Ecological Effects: Nontarget plant protection data requirements					
850.4400	Aquatic Plant Toxicity (<i>Lemna</i> spp.), Tiers 1 & 2				Waived (see endnote 6)
850.5400	Algal Toxicity, Tiers 1 & 2 – green alga				Waived (see endnote 7)
850.5400	Algal Toxicity, Tiers 1 & 2 – blue-green alga				Waived (see endnote 7)
850.5400	Algal Toxicity, Tiers 1 & 2 – diatoms, marine	48853101	Nufarm Americas, Inc.	PAY	See endnote 6
850.5400	Algal Toxicity, Tiers 1 & 2 – diatoms, freshwater	48853301	Nufarm Americas, Inc.	PAY	See endnote 6
158.1300: Environmental fate data requirements					
835.1230	Sediment and Soil Absorption/Desorption for Parent and Degradates				Waived
835.2120	Hydrolysis of Parent and Degradates as a Function of pH at 25C				Waived
835.2240	Direct Photolysis rate of Parent and Degradates in Water				Waived
835.1230	Sediment and Soil Absorption/Desorption for Parent and Degradates				Waived
835.2410	Photodegradation on Soil				Waived (see endnote 8)
835.4100	Aerobic Soil Metabolism			GAP	See endnote 9
835.4200	Anaerobic Soil Metabolism			GAP	See endnote 9
835.4300	Aerobic Aquatic Metabolism			GAP	See endnote 9
835.4400	Anaerobic Aquatic Metabolism			GAP	See endnote 9

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Ingredients:

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Non-Guideline Studies

N/A	Streptomycin Risk Assessment Study following the FDA Document #152 Guidance for Industry –grapefruit & tomatoes	49213202	Geo Logic Corp.	OWN	See endnote 10
N/A	Streptomycin Risk Assessment Study following the FDA Document #152 Guidance for Industry –Citrus	TBD	Geo Logic Corp.	OWN	
N/A	Benefits Discussion and Rationale supporting the addition of Grapefruit and Tomatoes for Firewall 17WP	49691201	Geo Logic Corp.	OWN	
N/A	Benefits Discussion and Rationale supporting the addition of Citrus for Firewall 17WP and Firewall 50 WP	TBD	Geo Logic Corp.	OWN	

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Endnotes for Data Matrix for Geo Logic Corp. Streptomycin Technical Fungicide/Bactericide Agricultural Streptomycin

¹ 830.7220 – Not applicable; the manufacturing use product is solid at room temperature.

² 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600, 870.3100, 870.3150, 870.3200, 870.3465, 870.3700, 870.3800, 870.4100, 870.4200, 870.5100, 870.5300, 870.5375, 870.5385, 870.5395, 870.6200, 870.6300, 870.7485, 870.7600, 870.7800 – These data requirements have been waived by EPA: “All toxicity data requirements are waived for streptomycin because of the extensive database in humans and animals that exists from the streptomycin drug use.” US EPA Final Work Plan Registration Review, May 2009, Case #0169.

³ Waiver request for Immunotoxicity study (870.7800) submitted in response to request by EPA.

⁴ 860.1300 –Nature of Residues in Plants: EPA Pesticide Fact Sheet No. 186, Streptomycin, Sept. 1988, Item No. 3. Science Findings, Physiological and Biochemical Characteristics: “Metabolism and Persistence in Plants and Animals: The Agency has determined that plant and animal metabolism data are not needed for the following reasons:

- metabolism of streptomycin in mammals has already been traced in connection with its use in humans;
- residues are non-detectable (< 0.5 ppm) in or on crops when treated according to label use rates and directions;
- large amounts of toxicological data exist;
- most crops are treated at or before transplanting (celery, peppers, potatoes and tomatoes) and pome fruit are treated foliarly but with a 30-day PHI for apples and crabapples;
- potential daily exposure to streptomycin as a pesticide is < 0.01% of the daily clinical dosage (1-4 grams/day).”

Additionally, neither Data Call-in (DCI) for Streptomycin Sulfate issued in 2008 or 2010 called for this study, nor is it indicated as a data gap on the final work plan for Streptomycin issued May 2009.

⁵ 860.1850 – According to the Streptomycin Reregistration Eligibility Document (RED), Appendix B, Sept. 1992, this data requirement is waived.

⁶ 835.1300, 835.1400, 835.2300, 835.4100, 835.4150, 835.4400, 835.5400 – The June 22, 2010 Data Call-In (DCI) for Streptomycin Sulfate called for these data. To address these data requirements, on October 1, 2010 Geo Logic issued an offer to Nufarm Americas, Inc. pursuant to FIFRA § 3(c)(2)(B) to jointly develop or share in the cost of developing these data.

⁷ Waiver confirmed in May 16, 2012 letter from Richard Keigwin (EPA) to Geo Logic.

⁸ 835.2410 - This data requirement is waived per the Reregistration Eligibility Document (RED) for Streptomycin and Streptomycin Sulfate, see Appendix B, page 5

⁹ 835.4100, 835.4200, 835.4300, 835.4400 – The June 22, 2010 DCI for Streptomycin Sulfate called for these data. Nufarm Americas, Inc. has submitted studies (currently in review) for 835.4100, 835.4200. After consultation with EPA, Nufarm Americas, Inc. will submit waiver requests for 835.4300 and 835.4400.

¹⁰ FDA Document #152 Guidance for Industry addresses potential effects of antibiotic resistance in response to the Agency’s request.